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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/972,016	10/04/2001	Tariq M. Rana	267/302	2378

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EXAMINER	
LUKTON, DAVID	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/972,016	RANA ET AL.	
	Examiner	Art Unit	
	David Lukton	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,16-29,31-33 and 35-37* is/are pending in the application.

4a) Of the above claim(s) *1-14 and 19-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-18,28,29,31-33 and 35-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Pursuant to the directives of the response filed 3/28/05, claims 28-29 have been amended. Claims 30 and 34 have been cancelled, and claims 35-37 added. Claims 1-14, 16-29, 31-33, 35-37 are now pending. Claims 1-14 and 19-27 remain withdrawn from consideration; claims 16-18, 28, 29, 31-33 and 35-37 are examined in this Office action.

Applicants' arguments filed 3/28/05 have been considered and found persuasive in part. The rejection of claims 16-18 and 28-34 under 35 U.S.C. §112, first paragraph (enablement) is withdrawn. The rejection of claims 15 and 29 under 35 U.S.C. §112 second paragraph is withdrawn. The previously imposed §103 rejections are now withdrawn.

✧

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-18, 28, 29, 31-33 and 35-37 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the specification as filed, the invention that is described requires that both of the following conditions be met: (a) the protein is labeled with a donor dye molecule, and (b)

the RNA is labeled with an acceptor dye molecule. Descriptive support for this is evident on page 10, paragraph 0026, and in (original) claim 15. Consider what claim 28 now recites. Claim 28 recites that the protein is labeled with a "first fluorescent dye molecule", and that the RNA is labeled with a "second fluorescent dye molecule". Accordingly, claim 28 encompasses both of the following two possibilities:

> (i) the protein is labeled with a donor fluorescent dye molecule, and concomitantly the RNA is labeled with an acceptor fluorescent dye molecule; and
>
> (ii) the protein is labeled with a acceptor fluorescent dye molecule, and concomitantly the RNA is labeled with a donor fluorescent dye molecule.

This ground of rejection is directed at the second of these two possibilities. There is no statement or suggestion anywhere in the specification that protein/RNA "interactions" can be determined, or should be determined when the protein is labeled with an "acceptor" fluorophore, while at the same time the RNA is labeled with a "donor" fluorophore.

In response to the foregoing, applicants have argued that they have provided a working example in which the protein is labeled with a fluorophore, and the RNA is also labeled with a fluorophore. Applicants have not identified the location in the text where descriptive support for this assertion can be found. At some point in the future, applicants may decide to point to example 4 (pages 13-14) as supporting their assertion that descriptive support is present for a protein bearing a fluorophore which is in close proximity to a ribonucleotide

bearing a fluorophore. In the event that applicants choose to point to this example, the argument by the examiner will be that, in this example, the peptide is labeled with a donor dye molecule, and the ribonucleotide is labeled with an acceptor dye molecule. Thus, applicants have not identified the location in the text which supports their assertions, but if the "working example" is that of example 4, it supports the examiner's position, rather than applicants'.

Applicants have also argued that the claimed invention is enabled, specifically that the specification enables a genus of embodiments in which the protein is labeled with an acceptor dye molecule and the RNA is labeled with a donor dye molecule. The examiner will stipulate that if a skilled peptide chemist, working together with a skilled spectroscopist had been presented with a copy of the specification on 10/4/00, **and if** that presentation were accompanied by a suggestion to reverse the position of the two probes, the two skilled chemists would then be able to reverse the position of the two probes, and to determine the extent of fluorescence energy transfer between. However, the fact that the chemists would have the skill to carry out the invention now proposed by applicants does not mean that the invention was described. For example, if the two chemists referred to above had been given a suggestion to place the donor fluorophore on a protein and the acceptor fluorophore on a **deoxy**ribonucleotide (i.e., DNA rather than RNA), the two chemists would be able to do this as well. There are numerous other variations that the

two chemists would be able to achieve, given the suggestion to do so. But the fact that the skilled artisan would be able to carry out experiments after having been given the suggestion to carry them out does not mean that those experiments were described in a specification in the absence of those suggestions. Such is the case here. Perhaps it was just an oversight on the part of applicants at the time the application was written. Or perhaps applicants believed at the time of writing that some advantage would accrue by placing the donor on the protein and the acceptor on the RNA. Or perhaps applicants believed that the degree of novelty would be greater if the donor were on the protein and the acceptor were on the RNA. Whether by inadvertent omission or by design, applicants did not include any suggestion in the application to place the donor on the RNA and the acceptor on the protein. The fact that the claimed invention might become enabled if adequately described does not change the fact that the claimed invention is not described. The rejection is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

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No claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached at 571-272-0925. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

DAVID LUKTON
PATENT EXAMINER
GROUP 1800